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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Alan David Wickenden

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/939,230	<b>Applicant(s)</b> WICKENDEN ET AL.	
	<b>Examiner</b> Leslie A. Royds	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-57, 60-62, 65-69 and 83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-57, 60-62, 65-69 and 83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>23 July 2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

**Claims 45-57, 60-62, 65-69 and 83 are presented for examination.**

**Applicant's petition for revival after unintentional abandonment filed June 26, 2008 has been received and entered into the present application and was granted November 3, 2008.**

Applicant's Amendment and Information Disclosure Statement (IDS) filed July 23, 2008 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08A&B (one page total), the Examiner has considered the cited references.

Claims 45-57, 60-62, 65-69 and 83 remain pending and under examination. Claim 45 is amended.

Applicant's arguments, filed July 23, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

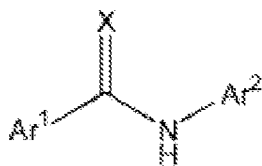
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-57, 60-62, 65-69 and 83 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for how to make the instantly claimed compounds of the formula recited in instant claim 45, does not reasonably provide enablement for the use of the same for the instantly claimed method for reducing anxiety by increasing ion flow through KCNQ potassium channels, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons

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of record set forth at p.2-10 of the previous Office Action dated December 18, 2007, of which said reasons are herein incorporated by reference.

Applicant's remarks and submissions filed July 23, 2008 have been fully considered and are sufficient to establish that the instant specification enables how to make the instantly claimed compounds



of Formula . However, the instant rejection remains proper over the instant claims because the specification, even in view of Applicant's amendments to the claims and the remarks filed July 23, 2008, fails to establish that the instant specification provides adequate direction as to how to use the instantly claimed compounds of the Formula *supra*.

#### *Response to Applicant's Arguments*

Applicant traverses the instant rejection, stating that the disclosure identified their compounds as anxiolytics based upon their KCNQ channel modulating abilities and further confirmed this nexus by testing one of the active compounds for anxiolytic activity *in vivo*. Applicant submits that the removal of the "recital at issue" is sufficient to obviate the rejection.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Though it is noted that Applicant has *identified* their compounds as anxiolytics based upon their KCNQ channel modulating ability, the fact remains that the instant specification fails to present any evidence, either in the form of data or scientifically sound reasoning, that would support the conclusion that the instantly claimed compounds actually do function to modulate KCNQ potassium channels and, therefore, would be functional to reduce anxiety. Applicant relies upon the mechanism of action (i.e., increasing ion flow through KCNQ potassium channels in a cell) underlying the purported biological activity to establish that the genus of compounds instantly claimed would have been useful for reducing

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anxiety in a subject in need thereof. In other words, Applicant's inventive concept rests upon the correlation between the particular activity of the claimed compounds and a reasonable expectation of efficacy in treating the claimed disease (i.e., in this case, anxiety). Though Applicant's Example 6, directed to an *in vivo* Geller conflict test for anxiolytics, demonstrates that the use of a compound with selective KCNQ2/3 channel opening activity increased punished responding in a dose-dependent manner by 40% or more at dosages of 30 and 56 mg/kg (an effective that is indicative of rapid-onset anxiolytic activity), Applicant has failed to demonstrate that the *instantly claimed compounds* actually function to achieve the claimed activity of increasing ion flow through KCNQ potassium channels in a cell. Although Applicant has presented an Example (see Example 6) using a selective KCNQ2/3 channel opener compound and did demonstrate that said compound had rapid-onset anxiolytic activity, Applicant never set forth the identity of this compound either by name or chemical structure. Thus, though Applicant asserts that this compound was "one of the active compounds" of the instant claims, there is no disclosure to support this allegation and, therefore, one of ordinary skill would not be imbued with a reasonable expectation of success in extrapolating whatever anxiolytic activity was seen with this test compound to any one or more of the other compounds instantly claimed because the identity of the test compound is unknown.

These facts coupled with the fact that the specification also fails to present either via a working example(s) or a clear, scientifically sound explanation as to what, in fact, enables the ion flux increase through KCNQ potassium channels such that the skilled artisan would have been imbued with at least a reasonable expectation of predictability of action in treating the claimed disorder (i.e., reducing anxiety in a subject in need thereof) by effecting this action using the full scope of compounds instantly claimed clearly support the conclusion of a lack of enabling direction provided in the instant specification as to how to use the instantly claimed compounds. This is because, absent such guidance, the experimentation required to determine if there is any activity of any of the compounds in treating the claimed disorder, and

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further, to determine, without needing to resort to random speculation, what therapeutic amounts would be available to even start testing for a therapeutic effect, would clearly be undue.

Moreover, though Applicant appears to believe that the amendment to remove the limitation of "able to increase ion flow through KCNQ potassium channels, said composition administered to the subject in a potassium channel-opening amount, thereby reducing anxiety in the subject" will overcome the instant rejection, Applicant is reminded that the instant claims are still directed to a method for reducing anxiety in a subject in need thereof by increasing ion flow through KCNQ potassium channels via administering the instantly claimed genus of compounds. Thus, the fact that Applicant has removed this limitation from the claims does not overcome the fact that the instantly claimed compounds must still be enabled to achieve the instantly claimed function of reducing anxiety via increasing ion flow through KCNQ potassium channels, which, for the reasons *supra* and those already of record, they are not.

For these reasons *supra*, and those previously made of record at p.2-10 of the Office Action dated December 18, 2007, rejection of claims 45-57, 60-62, 65-69 and 83 remains proper.

### ***Conclusion***

Rejection of claims 45-57, 60-62, 65-69 and 83 remains proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the

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advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/  
Patent Examiner, Art Unit 1614

March 8, 2009

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614